



America

CERTIFICATE

No. QS6 073936 0011 Rev. 03

Certificate Holder: Copan Italia S.p.A.
Via F. Perotti, 10
25125 Brescia
ITALY

Certification Mark:



Scope of Certificate: Design and Development, Manufacturing and Distribution of Medical and In-Vitro Diagnostic, Devices for Collection, Preservation and Transport of Biological Specimens including Swabs, Media and Specimen Receptacles

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_073936_0011_Rev.03

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: F001208
Report No.: ITA2066271
Effective Date: 2023-05-31
Expiry Date: 2025-02-11

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Date of Issue: 2023-06-19

(Renee Walker)
Director, US Certification Body, MHS

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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820
- 21 CFR Part 821

Facility(ies):

Copan Italia S.p.A.

Via F. Perotti, 10, 25125 Brescia, ITALY

Copan Italia S.p.A.

Via F. Perotti 18, 25125 Brescia, ITALY

Copan Italia S.p.A.

Via A. Grandi 27, 25125 Brescia, ITALY

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Facility Scopes:

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Copan Italia S.p.A. 116297

Via A. Grandi 27, 25125 Brescia, ITALY

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